APR 2 4 2001

K000442

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Prepared: February 4, 2000
Date Revised: April 18, 2001

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Contact Person: David B. Padget
Vice President

Device Name: Trade Name: *ACTI*-Gard® Antimicrobial Incise Drape
Common Name: Disposable Surgical Drapes
Classification: Surgical Drapes and Drape Accessories

Predicate Device: Ioban® 2 (iodophor) Antimicrobial Film, marketed by 3M Company, St. Paul, Minnesota

Device Description: *ACTI*-Gard® Antimicrobial Incise Drapes are thin polymeric materials coated with an adhesive containing 0.33% of the antimicrobial agent DIMTS (diiodo-sulfone)

Intended Use: Use *ACTI*-Gard® Antimicrobial Incise Drapes to reduce the risk of skin flora contamination throughout a surgical procedure.

Technological Characteristics: *ACTI*-Gard® Antimicrobial Incise Drapes apply the same technological characteristics as the predicate device. Both *ACTI*-Gard® Antimicrobial Incise Drapes and Ioban® 2 Antimicrobial Films consist of a thin plastic film coated with an acrylic-based, pressure sensitive adhesive, containing an antimicrobial agent. Both devices are intended to reduce the risk of skin flora contamination throughout the surgical procedure. Both devices are used as incise drapes.

Effectiveness:

Table X – Effectiveness Comparison of *ACTI*-Gard® and Ioban® 2

PROPERTY	MCD (*ACTI*-GARD® ANTIMICROBIAL INCISE DRAPES)	3M (IOBAN® 2 ANTIMICROBIAL FILM)
Physical Properties (Table III)	Equivalent	Equivalent
Antimicrobial Agent, DIMTS (Appendix E and L- Susceptibility Testing)	Tested Effective Against 21 Stock and Clinical Isolates of Post-Operative Organisms: (>3 log reduction at 10mins., 6hrs. and 24hrs.)	Tested Effective Against 14 Stock Organisms
Effectiveness Testing (Table IV – Seeded Pigskin)	Equivalent Log Reduction: (0 log in 10mins., 1.0 log in 30mins., and 2.5 log in 6hrs.)	Equivalent Log Reduction: (0 log in 10mins., 1.0 log in 30mins., and 2.5 log in 6hrs.)
Effectiveness Testing (Appendix M – Seeded Human Skin)	Equivalent Log Reduction: 3 organisms tested at 30 minute and 4 hour exposures	Equivalent Log Reduction: 3 organisms tested at 30 minute and 4 hour exposures
Effectiveness Testing (Appendix P – Zone of Inhibition)	Prevented Growth of All 14 Microorganisms Tested	Prevented Growth of All 14 Microorganisms Tested

The antimicrobial agent, DIMTS, in *ACTI*-Gard® Antimicrobial Incise Drapes was clinically evaluated for both safety and effectiveness using both laboratory stock and clinical isolates of organisms commonly associated with post-operative infection. The protocol for evaluating effectiveness, "Pre-Operative Skin Preparation Method, ASTM E1173-93", was modified by substituting pig skin for human. This modification was necessary for the type of organisms selected. Pig skin is a recognized skin substitute for in vivo applications.

Safety Testing:

Table XI – Safety Comparison of *ACTI*-Gard® and Ioban® 2

PROPERTY	MCD (*ACTI*-GARD® ANTIMICROBIAL INCISE DRAPES)	3M (IOBAN® 2 ANTIMICROBIAL FILM)[1]
Safety Testing (Animal, Table VIII and Appendix L)	Biocompatible	Biocompatible
Cumulative Skin Irritation (Human, Appendix G and L)	Mild to Moderate Irritant Response in Initial 200 Patient Study and Mild Irritant Response in 11% of Study Population for Second 200 Patient Study	Mild to Marked Irritant Response in 20% of Study Population for 200 Patient Study. 3M Reported, Minimally Irritating
Human Sensitization (Appendix G and L)	Non-sensitizing (200 patient study)	Low Potential for Sensitization
Sterilization Considerations	EtO & Gamma Compatible	Gamma Compatible, EtO Unstable (Wrapped in Foil)

[1] Information is found in Appendix L, 3M Antimicrobial 510(k) and technical articles.

ACTI-Gard® Antimicrobial Incise Drapes are used for topical applications. Biocompatibility test results demonstrate, mild skin irritation and no contact dermatitis or sensitization. DIMTS is a stable molecule and is effective at low concentrations (0.33%), providing a safe environment for the patient. During irrigation, the low water solubility of DIMTS (0.0001 g/L) reduces the potential exposure of intracutaneous tissues to DIMTS. The high decomposition temperature (350° F) assures safety and stability of the material during processing and sterilization.

***Additional safety data**: in addition to the above safety testing, MCD has sold internationally 22,090 ACTI-Gard® Antimicrobial Incise Drapes, with CE marking, since December 1996. No clinical or product complaints have been received by MCD or authorized representatives during this period.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2001

Mr. David Padget
Vice President
Medical Concepts Development, Incorporated
2500 Ventura Drive
Woodbury, Minnesota 55125-3927

Re: K000442
Trade/Device Name: Acti-Gard® Antimicrobial Incise Drapes
Regulation Number: 878.4370
Regulatory Class: II
Product Code: KKX
Dated: January 30, 2001
Received: January 31, 2001

Dear Mr. Padget:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000442

Device Name: ACTI-Gard® Antimicrobial Incise Drape

Indications For Use:

Use ACTI-Gard® Antimicrobial Incise Drapes to reduce the risk of skin flora contamination throughout a surgical procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K000 442